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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,602	12/31/2003	Daryll A. Emery	293.00010102	8548

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,602	EMERY ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-82* is/are pending in the application.

4a) Of the above claim(s) *45-66 and 70-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-44 and 67-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/9/04,8/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.0.0

DETAILED ACTION

Claims 34-82 are pending in the application.

Applicant's election with traverse of Group III, claims 34-44 and 67-82 in the reply filed on 4/18/05 is acknowledged. The traversal is on the ground(s) that the groups would not be a Burdon to search. This is not found persuasive because as indicated in the original Restriction requirement, the search for each group is not co-extensive, particularly with regard to the non-patented literature search.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of the species enterochelin in the reply filed on 4/18/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Because claims 70-82 are directed toward the non-elected species (these claims are drawn to wherein the immunogen comprises a siderophore receptor protein from a gram-positive bacterium; Applicant elected enterochelin, which is a siderophore receptor protein from a gram-negative bacterium; i.e., e. coli or Salmonella) these claims are hereby withdrawn from the merits.

Claims 45-66 are further withdrawn from the merits as they are directed toward a non-elected invention elected with traverse in the response filed 4/18/05.

Claims 34-44 and 67-69 were examined on their merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-44 and 67-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. US 6,682,754. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Instant claims are made obvious by claims 1-14 of '754.

Claims 1-14 of '754 teach a method for inducing immunity in a bird via implantation in ovo of a biocompatible implant providing for delayed and sustained release of an immunogen, wherein the implant is injected during the fourth quarter of incubation, during 15-28 days of incubation and day 17-19 of incubation of an egg and wherein the implant provides for sustained release of the immunogen for about 1-90 days or 1-60 days or 1-35 days post-hatching.

The claims of 1-14 do not specifically teach wherein the immunogen is a siderophore receptor such as enterochelin. However, the patent teaches that a preferred immunogen is enterochelin (see col. 10 line 45). Therefore, enterochelin is encompassed by the term 'immunogen'.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34, 37 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emery et al. (US 5,830,479) in view of Phelps et al. (US 5, 339,766).

Emery et al. (US 5,830,479) disclosed a method for immunizing poultry with a siderophore from gram-negative bacteria wherein the siderophore is enterochelin or siderophore citrate as examples (col.s 1-53, particularly col. 5, lines 29-38 and claims 1 and 3). As stated by Emery et al. "The vaccine of the present invention may be used for preventing and eliminating infections of gram-negative bacteria in poultry and other animals including humans" (col. 11, lines 9-12). Emery et al. specifically suggested sustained release administration of the vaccine (col. 11, line 15) and *in-ovo* administration in poultry (aka 'egg inoculation' – see col.11, line 16). Emery et al. specifically taught that "The protein may also be incorporated into a carrier which is a [*sic*] biocompatible and can incorporate the protein and provide for its controlled release or delivery, for example, a sustained release polymer such as a hydrogel, acrylate, polylactide, polycaprolactone, polyglycolide or copolymer thereof...an example of a solid matrix for implantation into the animal and sustained release of the protein antigen into the body is a matabolizable matrix, as described...in US ...4,452,775 (Kent)" (col. 11, lines 27-36). Emery et al. also taught the advantageous use of a booster vaccine given "21-28 days after the first injection".

Emery et al. did not specifically teach wherein the siderophore receptor was administered *in-ovo* at 'a time when maternal antibodies of the bird to the immunogen are sufficiently reduced'. Nor did Emery et al. teach the specific injection times as found in claims 39-42 and 44 or wherein a second dose of immunogen was given at 3-12 weeks post-hatching (claim 43).

Phelps et al. (US 5, 339,766) disclosed a method for introducing mat6erinl into poultry eggs during early embryonic development which included injection of a therapeutic substance contained within a biodegradable matrix such as polylactide polymers (lactides/glycolides) directly into the developing bird egg. Materials intended for delivery included "vaccines, vitamins, antibiotics hormones, enzyme inhibitors, peptides, cells, DNA and other therapeutic molecules" (col. 3, lines 33-36). Phelps et al. discussed that, "Eggs treated by the method of the present invention are preferably fertile eggs which may be in any period of incubation, from early to late... " (col. 4, lines 15-18). Phelps et al. further explained that "Such beneficial effects included increased growth, disease resistance due to in ovo vaccination, increased percentage hatch of multiple incubated eggs, and otherwise improved physical characteristics of hatched poultry" (col. 1, lines 20-24).

It is well known in the art that newborn mammals such as poultry have weakened immune systems. Because these newborns have not been challenged with disease-causing bacteria/viruses, they do not have the antibodies to protect them against such foreign invaders.

One of ordinary skill in the art would have been motivated to administer a sustained-release formulation *in ovo*, to a bird (i.e., poultry such as chicken) wherein the formulation comprised a siderophore receptor such as enterochelin, and wherein the

sustained-release formulation was sustained until the hatching of the bird (i.e., 1-60 or 1-90 days post-hatching) in order to increase the bird's immune system to foreign disease causing bacteria. It was clear from the prior art that siderophore receptors from gram-negative bacteria were known to vaccinate birds, and suggested for use in-ovo by Emery et al. Further disclosed by Emery et al. as well as Phelps et al. were suitable mediums and sustained release biocompatible matrices for in-ovo injection of vaccines. The ordinary artisan would have recognized that the most crucial time of vaccination delivery to a young bird is within the first few days of life and hence would have had a reasonable expectation that formulating a biocompatible matrix which sustained the release of enterochelin would have been beneficial to the health of the bird, in that the bird, upon injection with the enterochelin, would create antibodies to the gram-negative bacteria thereby increasing the bird's immune system to that bacteria.

One of ordinary skill in the art would have been motivated to administer a booster shot of siderophore receptor 3-12 weeks of hatching, in order to boost the immune system of the young bird. Emery et al. makes it clear that a booster is advantageously administered 21-28 days after the first injection.

Claims 34-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emery et al. (US 5,830,479) in view of Phelps et al. (US 5, 339,766) and further in view of Evans et al. (US 6,500,438 B2).

The teachings of Emery et al. and Phelps et al. were discussed *supra*. Neither reference taught the specific injection protocols as recited in claims 35, 36, 38 and 44.

Evans et al. (US 6,500,438 B2) taught a method for *in ovo* vaccination of chickens with *E. sporozoites* via injection, wherein the injection was preferentially performed in the final quarter of incubation or specifically at day 18 of incubation, however would have been effective during any time of incubation (col. 2, lines 1-6, col. 3 lines 25-27 and Example 1).

Although the prior art did not teach the specific injection times, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Although the prior art do not teach all the various permutations of injection times/release times, it would be conventional and within the skill of the art to identify the optional administration times as well as release times because (1) it was well known in the art that newborn mammals have weakened immune systems, (2) *in-ovo* administration of enterochelin to challenge the immune systems of incubating poultry embryos was clearly suggested by Emery et

al. and arginine and (3) sustained delivery systems for vaccines; i.e., biocompatible polymer coatings/matrices were known and suggested for in-ovo delivery of vaccines.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary and absent any unexpected results.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

7/19/05